



**U.S. Army Medical Materiel Agency
(USAMMA)/Distribution Operations Center (DOC)**

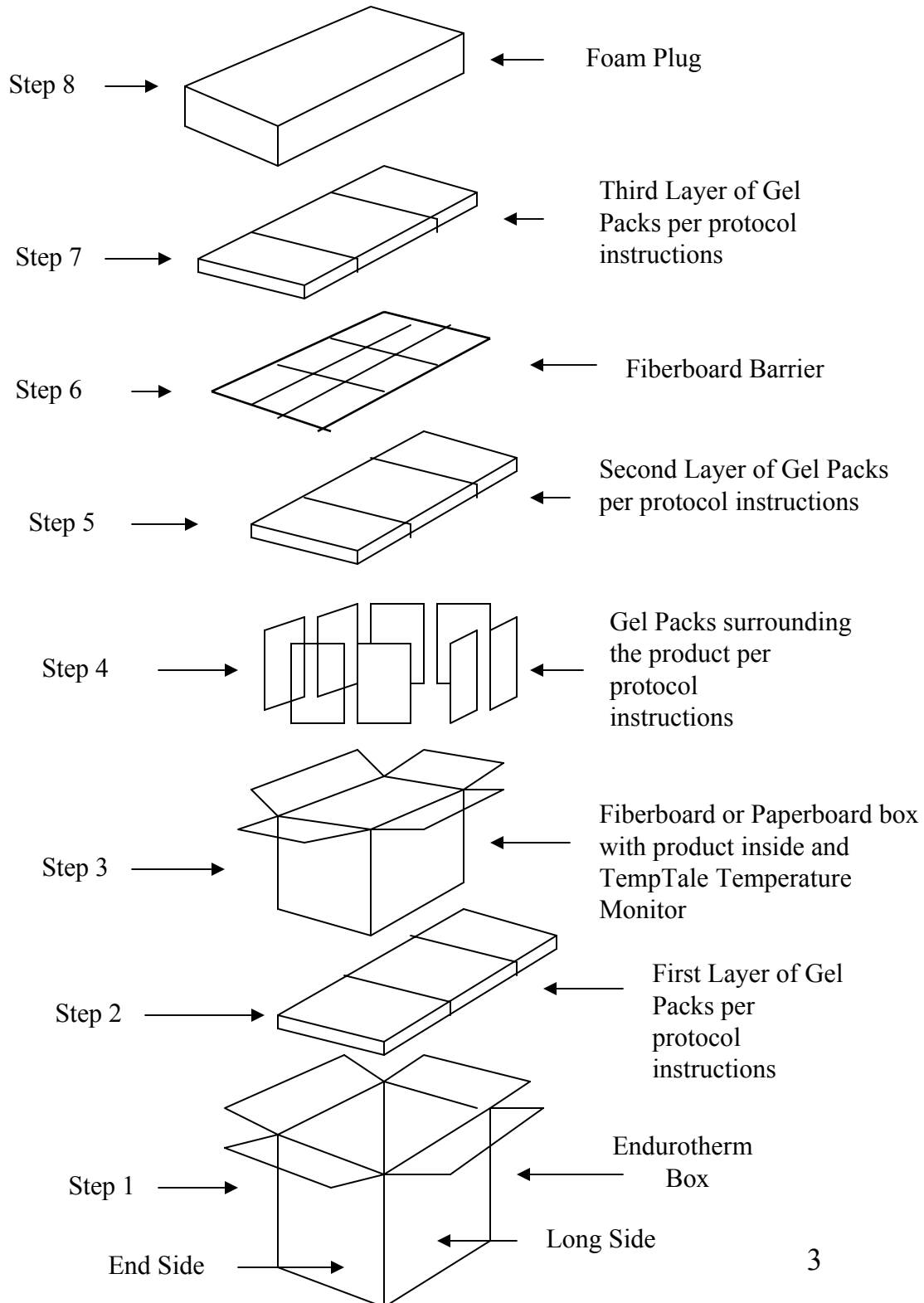
**Packing Protocols for Temperature
Sensitive Medical Products requiring
Storage and Transportation
Temperatures between
2°C - 8°C (36°F - 46°F).**

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Endurotherm (ISC) Box Packing Steps

The packing or layering of the Endurotherm boxes is the same in principle for all three sizes (large, medium and small).



Cold Weather Packing Protocol

- Cold Weather Configuration is used when the ambient temperature at the **receiving site** is consistently below 55° F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2° C to 8° C within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and void space filler.
- Coolant material must be placed in layers according to attached diagrams. Cold Weather configurations only use refrigerated gel packs. (See cold weather packing configuration diagrams.)

Cold Weather Packing Protocol Procedures

The Cold Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site consistently remains below 55 degrees Fahrenheit. Begin the Cold Weather packing protocol by:

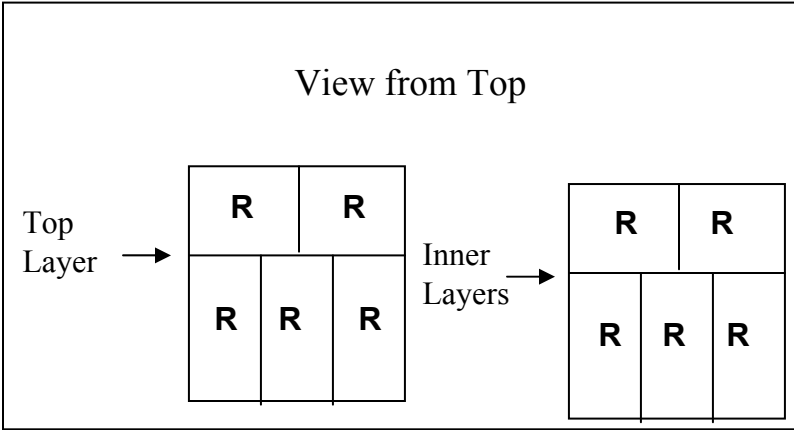
- o Placing a layer of refrigerated gel packs at the bottom of the box.
- o Next item will be the product.
- o Place refrigerated gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- o This is followed by placing an activated TempTale electronic temperature monitor on top of the product, activate the TempTale temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale and place it centered on top of the product.
- o Follow with another layer of refrigerated gel packs.
- o Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- o Add a final layer of refrigerated gel packs above the fiberboard barrier.
- o Finally, insert the foam plug to seal the contents of the box.

Notes:

- o Follow procedures according to each protocol diagram of ISC box used.
- o To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
- o To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.

Extra Large (ISC Box, E-327) – Cold Weather Packing Protocol Diagrams

Total amount of chilled Gel Packs = 27
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



Layer 3:

5 Large Refrigerated Gel Packs (48 oz. each)

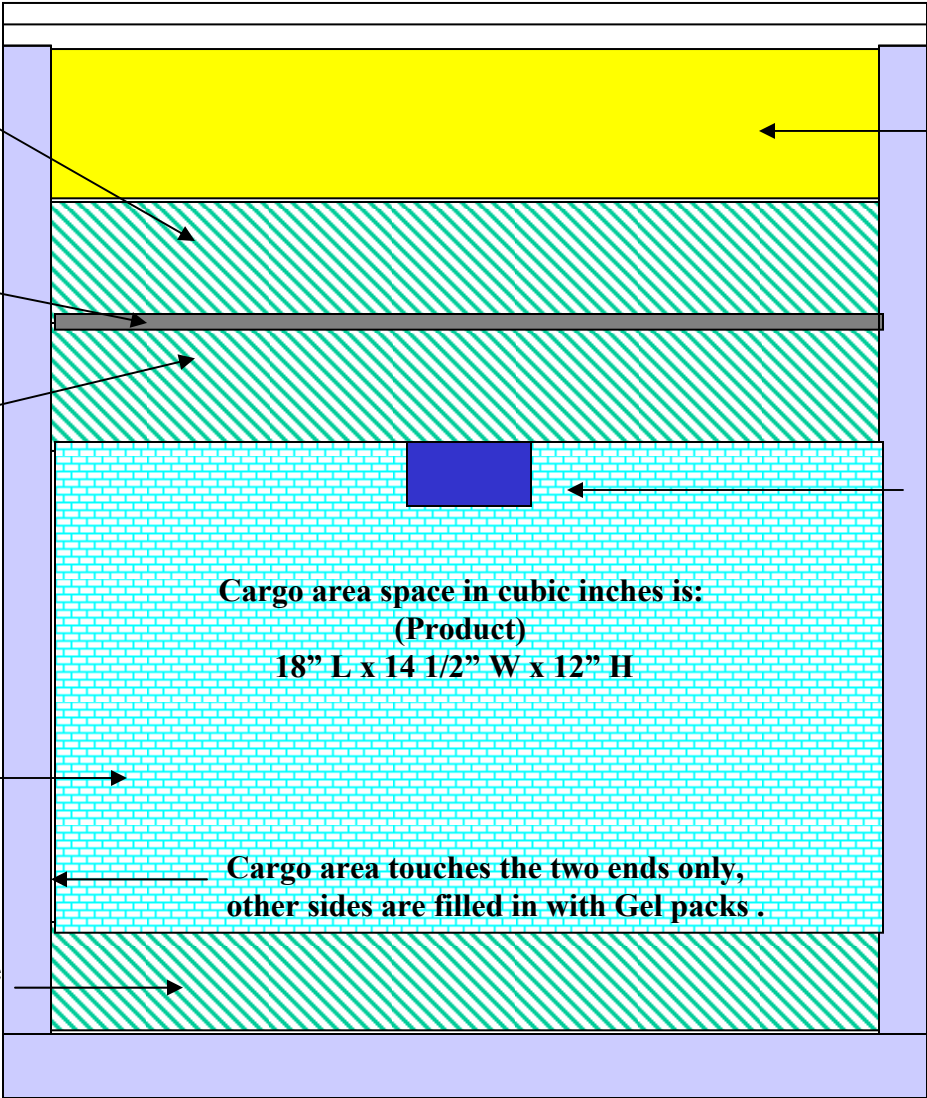
Fiberboard Barrier

Layer 2:

5 Large Refrigerated Gel Packs (48 oz. each)

Use a total of 12 Large Refrigerated Gel Packs (6 on each long side 48 oz. Each)

Layer 1: 5 Large Refrigerated Gel Packs (48 oz. each)



Foam Plug

Temperature Monitor

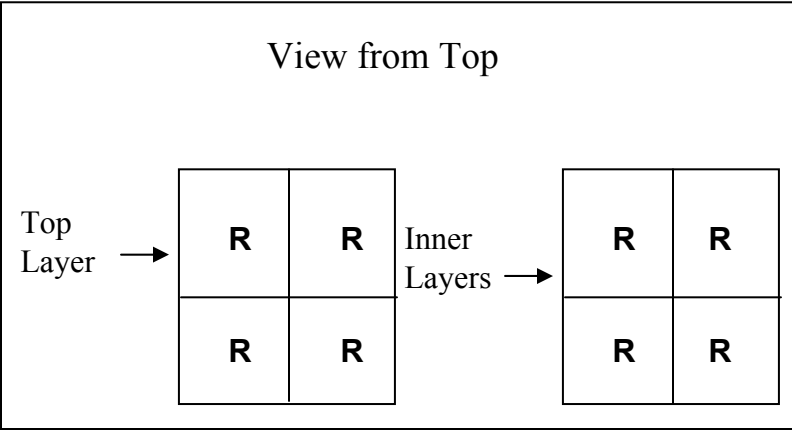
Cargo area space in cubic inches is:
(Product)
18" L x 14 1/2" W x 12" H

Cargo area touches the two ends only, other sides are filled in with Gel packs .

Side View

Large (ISC Box, E-186) – Cold Weather Packing Protocol Diagrams

Total amount of chilled Gel Packs = 17
Approximate Weight:
Max load = 75 lbs
Min load = 50 lbs



Layer 3:

4 Large Refrigerated Gel Packs (48 oz. each)

Fiberboard Barrier

Foam Plug

Layer 2: 4 Large Refrigerated Gel Packs (48 oz. each)

Temperature Monitor

Cargo area space in cubic inches is:
(Product)
16 ½" L x 12" W x 7" H

Use a total of 5 Large Refrigerated Gel Packs (2 in one end and 3 in one long side 48 oz each)

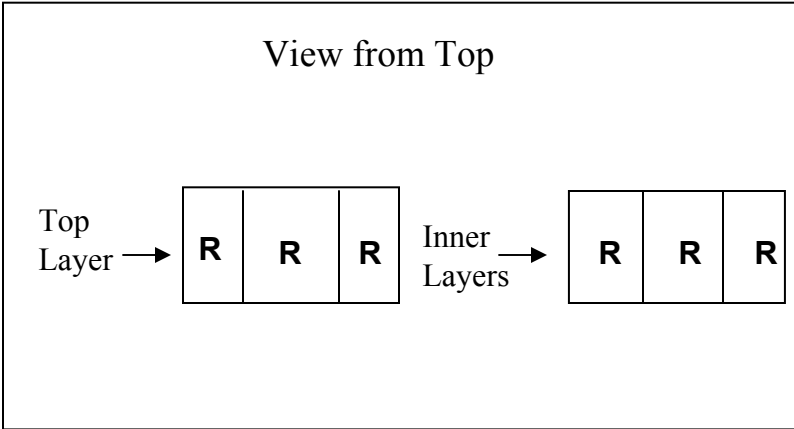
Cargo area touches one end and one long side only, other sides are filled in with Gel packs.

Layer 1: 4 Large Refrigerated Gel Packs (48 oz. each)

Side View

Medium (ISC Box, E-65) – Cold Weather Packing Protocol Diagrams

Total amount of chilled Gel Packs = 13
Approximate Weight:
Max load = 40 lbs
Min load = 30 lbs



Layer 3:

3 Medium Refrigerated Gel Packs (24 oz. each)

Fiberboard Barrier

Foam Plug

Layer 2:

3 Medium Refrigerated Gel Packs (24 oz. each)

Cargo area space in cubic inches is:
(Product)
12”L x 6 1/2” W x 6 1/2” H

Temperature Monitor

Use a total of 4 refrigerated Medium Gel Packs (2 in one long side and 2 in one end 24 oz. each)

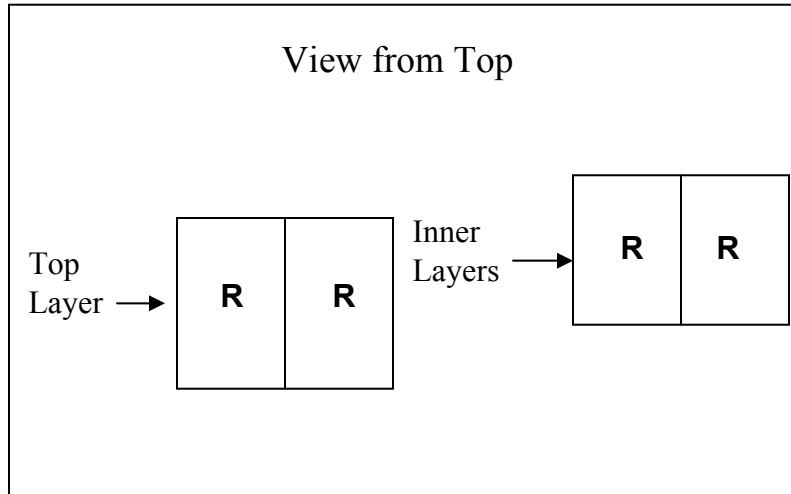
Layer 1:

3 Medium Refrigerated Gel Packs (24 oz. each)

Cargo area touches one end and one long side only, other sides are filled in with Gel Packs.

Side View

Small (ISC Box E-36-2) – Cold Weather Packing Protocol Diagrams



Total amount of chilled Gel Packs = 8

Approximate Weight:

Max load = 20 lbs

Min load = 15 lbs

Layer 3:

2 Medium Refrigerated Gel Packs (24 oz. each)

Fiberboard Barrier

Layer 2:

2 Medium Refrigerated Gel Packs (24 oz. each)

Layer 1:

2 Medium Refrigerated Gel Packs (24 oz. each)

Foam Plug

Temperature Monitor

2 Medium Refrigerated Gel Packs in one long side only (24 oz each).

**Cargo area space in cubic inches is:
(Product)
10 3/4" L x 6 1/2" W x 4" H**

Cargo area touches the two ends and one long side only, other side is filled in with Gel Packs.

Side View

Moderate Weather Packing Protocol

- Moderate Weather Configuration is used when the ambient temperature **at the receiving site** is between 55° F and 77° F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2° C to 8° C within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and fill in.
- Coolant material must be placed in layers according to attached diagrams.
Frozen gel packs are always farthest away from vaccine.

Moderate Weather Packing Protocol Procedures

The Moderate Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is between 55 degrees Fahrenheit and 77 degrees Fahrenheit. Begin the Moderate Weather packing protocol by:

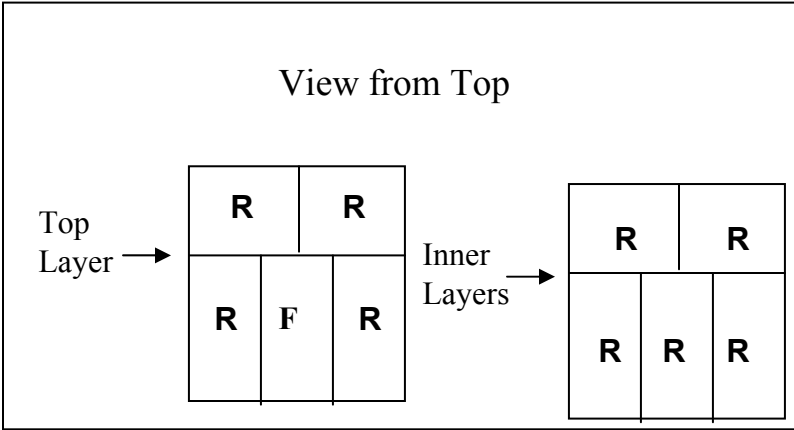
- o Placing a layer of refrigerated gel packs at the bottom of the box.
- o Next item will be the product.
- o Place refrigerated gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- o This is followed by placing an activated TempTale electronic temperature monitor on top of the product, activate the TempTale temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale and place it centered on top of the product.
- o Follow with another layer of refrigerated gel packs.
- o Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- o Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.
- o Finally, insert the foam plug to seal the contents of the box.

Notes:

- o Follow procedures according to each protocol diagram of ISC box used.
- o To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
- o To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.
- o To freeze large amounts of gel packs at once, place gel pack boxes inside a freezer that has been set to -17°C for at least 30 days prior use.
- o To quickly freeze small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

**Extra Large (ISC Box, E-327) – Moderate Weather Packing Protocols
Diagrams**

Total amount of Gel Packs:
Chilled = 26
Frozen = 1
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



Layer 3: 1

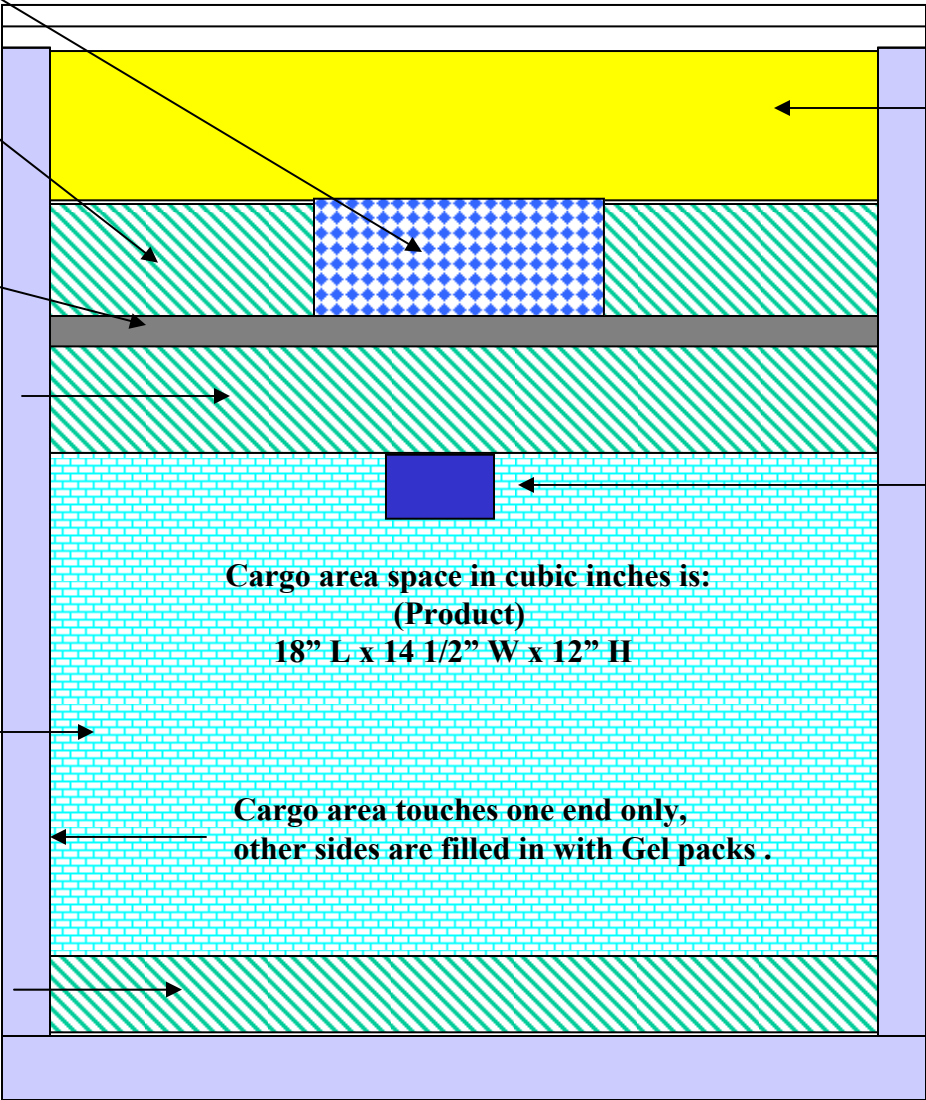
Large Frozen &
4 Large
Refrigerated Gel
Packs (48 oz.
each)

Fiberboard
Barrier

Layer 2: 5 Large
Refrigerated Gel
Packs (48 oz.
each)

Use a total of 12
Large
Refrigerated
Gel Packs
(6 on each
long side 48 oz.
Each)

Layer 1: 5 Large
Refrigerated Gel
Packs (48 oz.
each)



Foam Plug

Temperature
Monitor

Cargo area space in cubic inches is:
(Product)
18" L x 14 1/2" W x 12" H

**Cargo area touches one end only,
other sides are filled in with Gel packs .**

Side View

Large (ISC Box, E-186) – Moderate Weather Packing Protocols Diagrams

Total amount of Gel Packs:

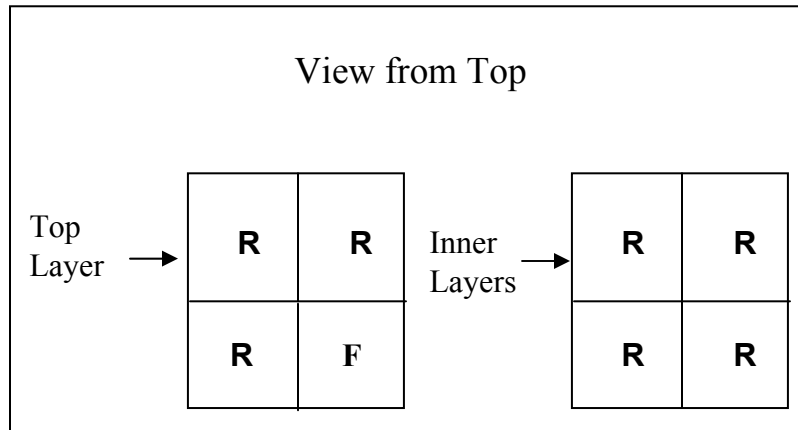
Chilled = 16

Frozen = 1

Approximate Weight:

Max load = 75 lbs

Min load = 50 lbs



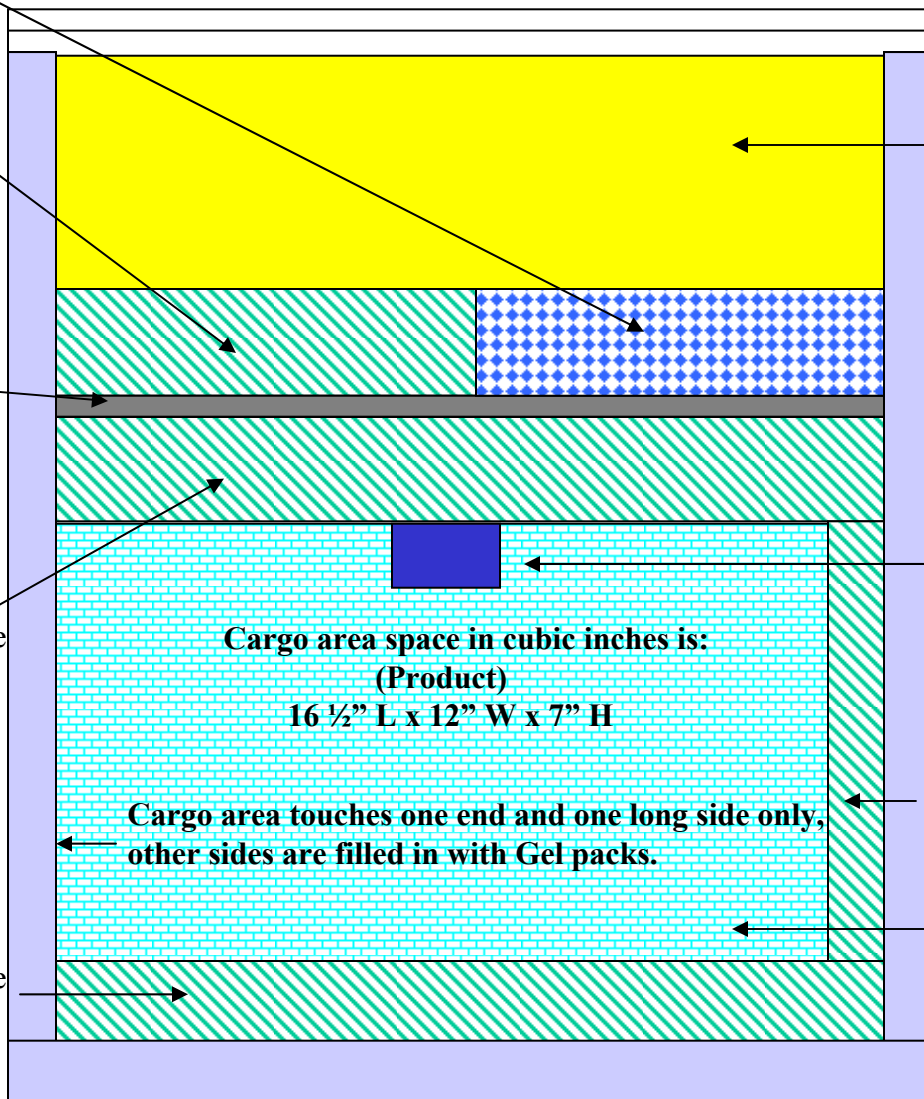
Layer 3:

1 Large Frozen Gel Pack & 3 Large Refrigerated Gel Packs (48 oz. each)

Fiberboard Barrier

Layer 2: 4 Large Refrigerated Gel Packs (48 oz. each)

Layer 1: 4 Large Refrigerated Gel Packs (48 oz. each)



Foam Plug

Temperature Monitor

Cargo area space in cubic inches is:
(Product)
16 ½" L x 12" W x 7" H

Cargo area touches one end and one long side only, other sides are filled in with Gel packs.

Use a total of 5 Large Refrigerated Gel Packs (2 in one end and 3 in one long side 48 oz each)

Side View

Medium (ISC Box, E-65) – Moderate Weather Packing Protocols Diagrams

Total amount of Gel Packs = 13

Chilled = 12

Frozen = 1

Approximate Weight:

Max load = 40 lbs

Min load = 30 lbs

View from Top



Layer 3:

1 Medium Frozen Gel Pack & 2 Medium Refrigerated Gel Packs (24 oz. each)

Fiberboard Barrier

Foam Plug

Temperature Monitor

Layer 2:

3 Medium Refrigerated Gel Packs (24 oz. each)

Use a total of 4 Refrigerated Medium Gel Packs (2 in one long side and 2 in one end 24 oz. each)

Layer 1:

3 Medium Refrigerated Gel Packs (24 oz. each)

Cargo area space in cubic inches is:
(Product)
12"L x 6 1/2" W x 6 1/2" H

Cargo area touches one end and one long side only, other sides are filled in with Gel Packs.

Side View

Small (ISC Box E-36-2) – Moderate Weather Packing Protocols Diagrams

Total amount of Gel

Packs = 8

Chilled = 7

Frozen = 1

Approximate Weight:

Max load = 20 lbs

Min load = 15 lbs

Layer 3:

1 Medium
Frozen Gel Pack
& 1 Medium
Refrigerated Gel
Pack (24 oz.
each)

Fiberboard
Barrier

Layer 2:

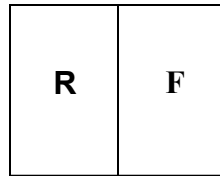
2 Medium
Refrigerated Gel
Packs (24 oz.
each)

Layer 1:

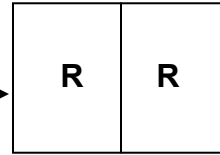
2 Medium
Refrigerated Gel
Packs (24 oz.
each)

View from Top

Top
Layer



Inner
Layers



Foam
Plug

Temperature
Monitor

2 Medium
Refrigerated Gel
Packs in one long
side only (24 oz
each).

Cargo area space in cubic inches is:
(Product)
10 3/4" L x 6 1/2" W x 4" H

**Cargo area touches the two ends and one long
side only, other side is filled in with Gel Packs.**

Side View

Warm Weather Packing Protocol

- Warm Weather Configuration is used when the ambient temperature **at the receiving site** is consistently above 77° F.
- Protocols are designed to keep temperature sensitive products requiring refrigeration temperatures between 2° C to 8° C within these temperature ranges during transportation, for up to 72 hours.
- 48 oz. and 24 oz. gel packs are used in all boxes for layering and fill in.
- Coolant material must be placed in layers according to diagrams. **Frozen packs are always farthest away from vaccine.**

Warm Weather Packing Protocol Procedures

The Warm Weather Packing Protocol is used whenever the ambient or outside temperature at the receiving site is consistently above 77 degrees Fahrenheit. Begin the Warm Weather packing protocol by:

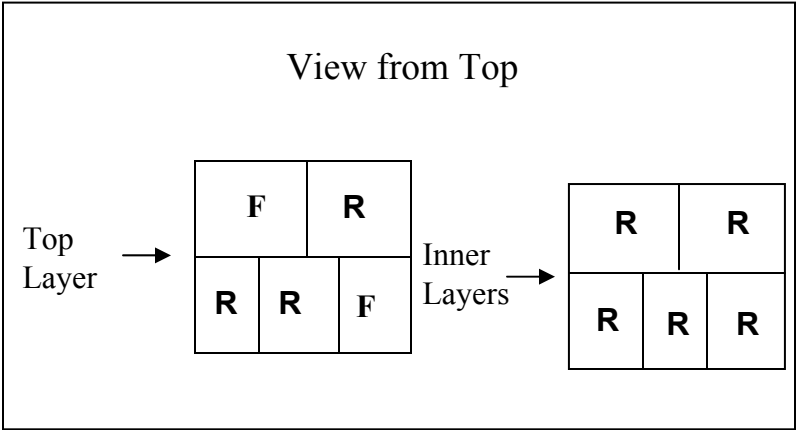
- o Placing a layer of refrigerated gel packs at the bottom of the box.
- o Next item will be the product.
- o Place refrigerated gel packs around the product's side(s) to fill in gap between product and the insulated walls of the box.
- o This is followed by placing an activated TempTale electronic temperature monitor on top of the product, activate the TempTale temperature monitor by pressing and releasing the "start" button. Once the button is released, a "sunshine" icon will appear in the upper left corner of the LCD. This indicates that the monitor is running. Peel off the tape in the back of the TempTale and place it centered on top of the product.
- o Follow with another layer(s) of refrigerated gel packs.
- o Above the second layer of refrigerated gel packs insert a fiberboard barrier.
- o Add a final layer of a combination of refrigerated and frozen gel packs above the fiberboard barrier.
- o Finally, insert the foam plug to seal the contents of the box.

Notes:

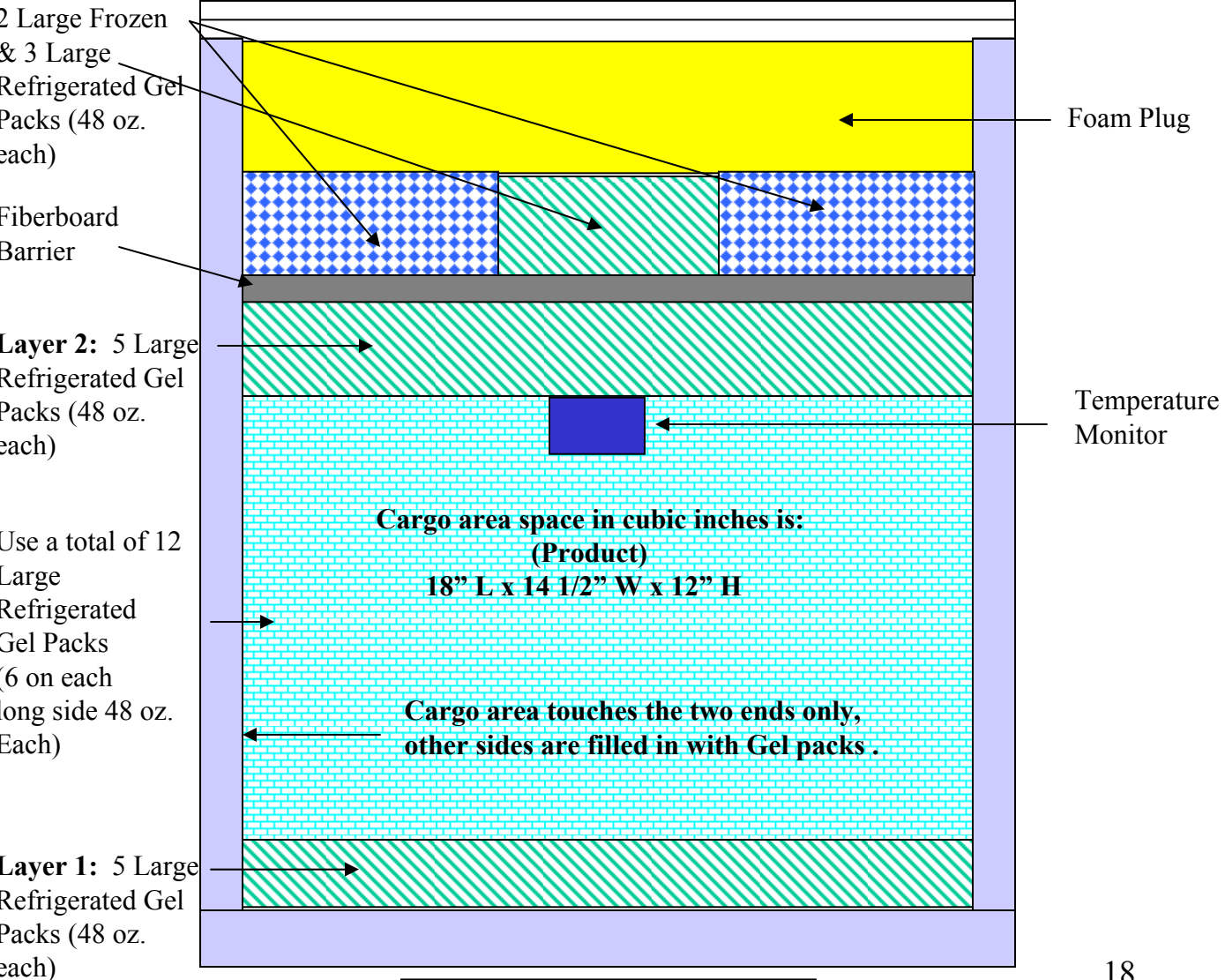
- o Follow procedures according to each protocol diagram of ISC box used.
- o To chill large amounts of gel packs at once, place gel pack boxes inside a refrigerator that has been set to 4° C for at least 30 days prior to use.
- o To quickly chill small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior use.
- o To freeze large amounts of gel packs at once, place gel pack boxes inside a freezer that has been set to -17°C for at least 30 days prior use.
- o To quickly freeze small amounts of gel packs, place them in a single layer inside a refrigerator as explained above for at least 24 hours prior to use (lay them flat to ensure they maintain their original shape once they are frozen) .

Extra Large (ISC Box, E-327) – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 27
Chilled = 25
Frozen = 2
Approximate Weight:
Max load = 145 lbs
Min load = 120 lbs



Layer 3:



Side View

Large (ISC Box, E-186) – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs:

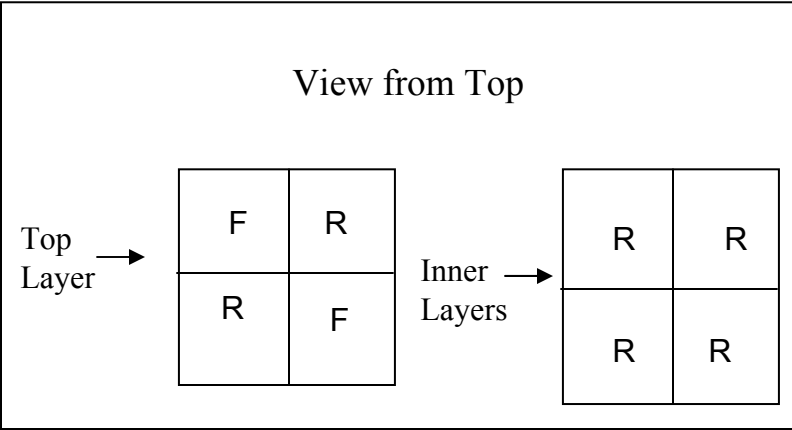
Chilled = 15

Frozen = 2

Approximate Weight:

Max load = 75 lbs

Min load = 50 lbs



Layer 3:

2 Large Frozen Gel Packs &
2 Large Refrigerated Gel Packs (48 oz. each)

Fiberboard Barrier

Layer 2: 4 Large Refrigerated Gel Packs (48 oz. each)

Layer 1: 4 Large Refrigerated Gel Packs (48 oz. each)

Foam Plug

Temperature Monitor

Use a total of 5 Large Refrigerated Gel Packs (2 in one end and 3 in one long side 48 oz each)

**Cargo area space in cubic inches is:
(Product)
16 ½" L x 12" W x 7" H**

Cargo area touches one end and one long side only, other sides are filled in with Gel packs.

Side View

Medium (ISC Box, E-65) – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 13

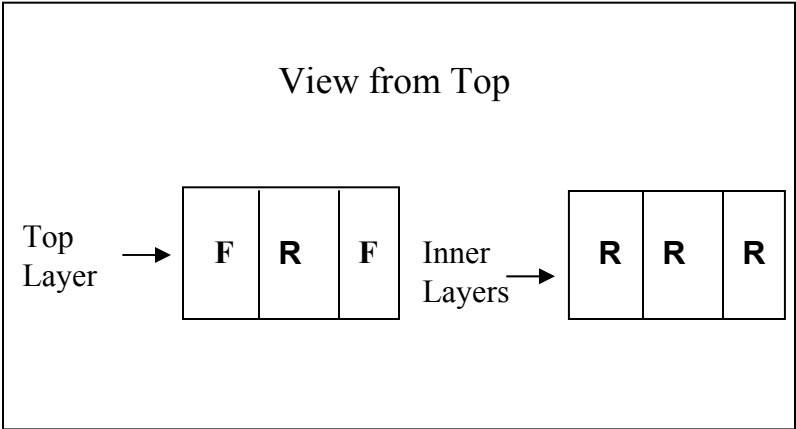
Chilled = 11

Frozen = 2

Approximate Weight:

Max load = 40 lbs

Min load = 30 lbs



Layer 3: 2

Medium Frozen
Gel Packs &

1 Medium
Refrigerated Gel
Pack (24 oz.
each)

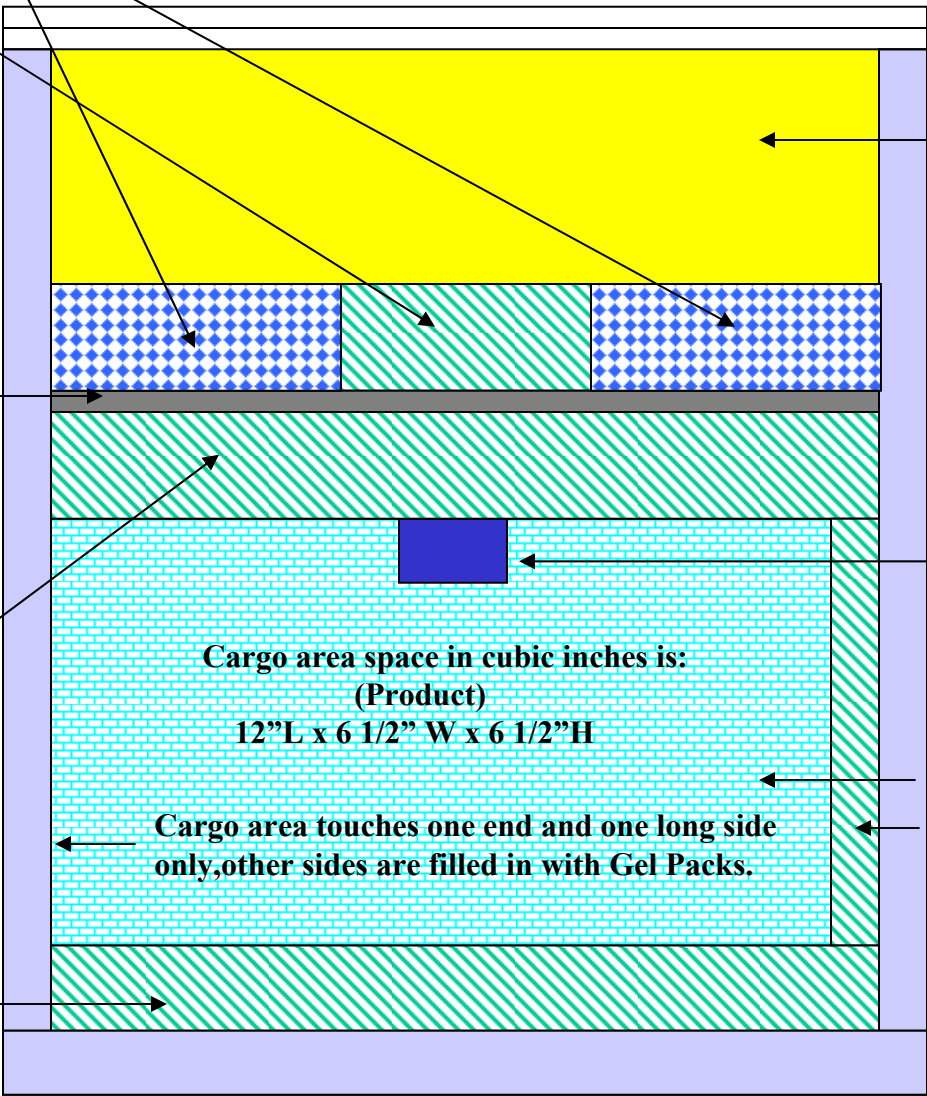
Fiberboard
Barrier

Layer 2:

3 Medium
Refrigerated Gel
Packs (24 oz.
each)

Layer 1:

3 Medium
Refrigerated Gel
Packs (24 oz.
each)



Foam Plug

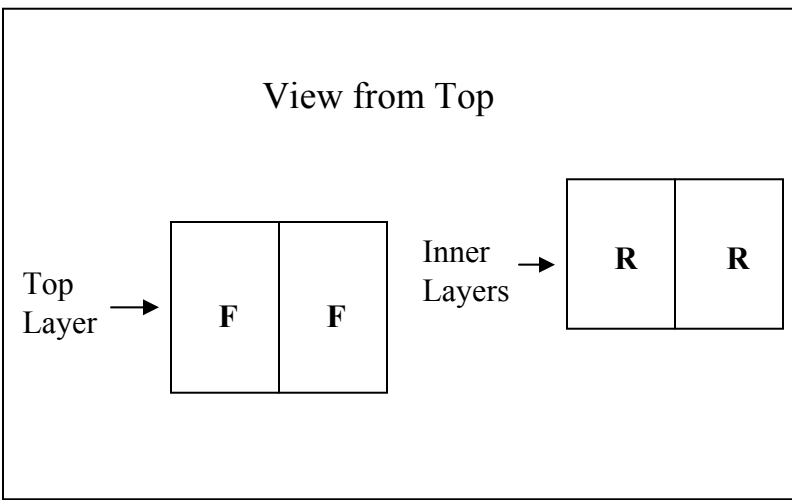
Temperature
Monitor

Use a total of 4
Refrigerated
Medium Gel
Packs (2 in one
long side and 2
in one end 24 oz.
each)

Side View

Small (ISC Box E-36-2) – Warm Weather Packing Protocol Diagrams

Total amount of Gel Packs = 8
Chilled = 6
Frozen = 2
Approximate Weight:
Max load = 20 lbs
Min load = 15 lbs



Layer 3:

2 Medium Frozen Gel Packs (24 oz. each)

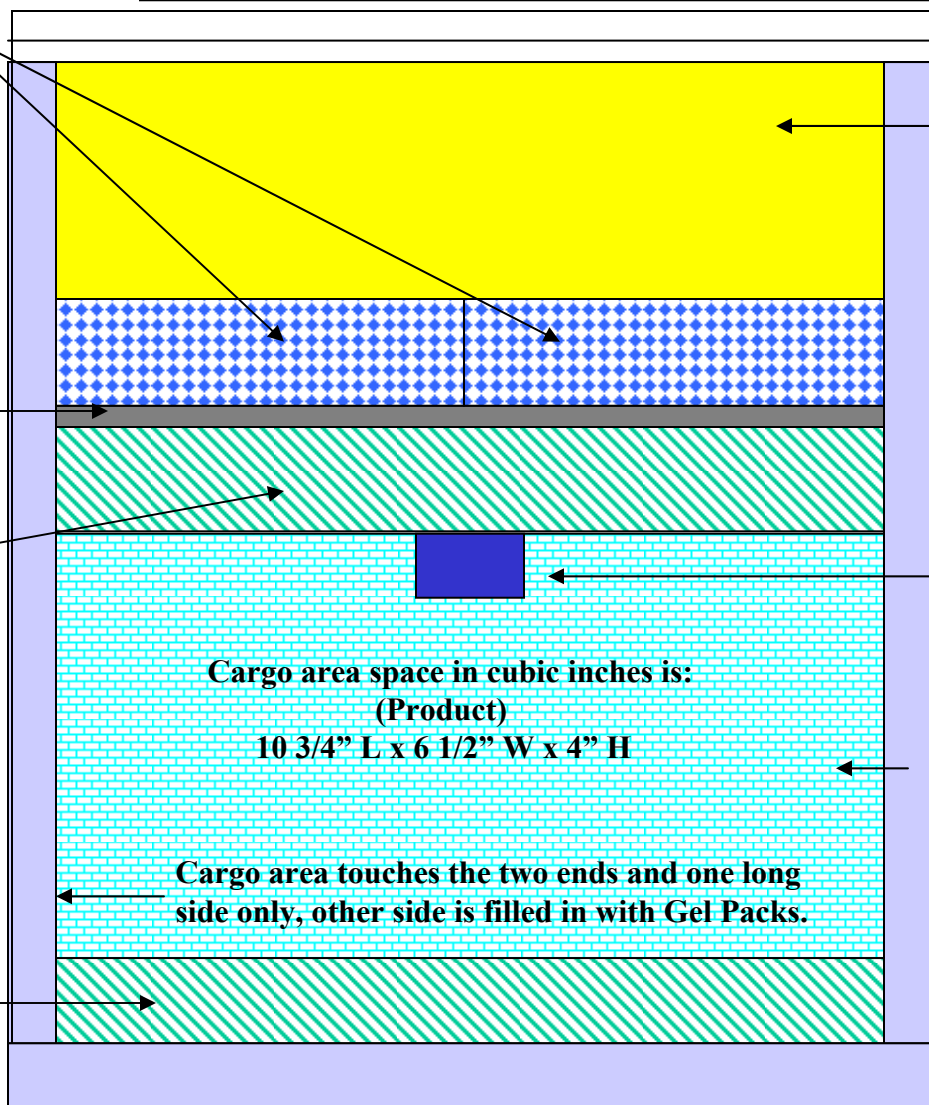
Fiberboard
Cardboard
Barrier

Layer 2:

2 Medium Refrigerated Gel Packs (24 oz. each)

Layer 1:

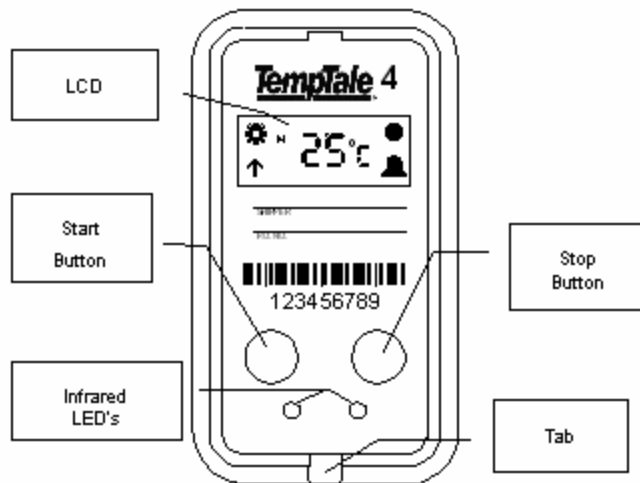
2 Medium Refrigerated Gel Packs (24 oz. each)



Side View

Starting a TempTale 4 Monitor

Hold down the start button (the green button on the monitor) until you see the sunshine icon (picture) on the upper left corner of the LCD that confirms that the monitor has started. When the monitor is activated, the sunshine icon will stay on until the monitor has been stopped. The monitor will begin recording data after the startup delay is completed.

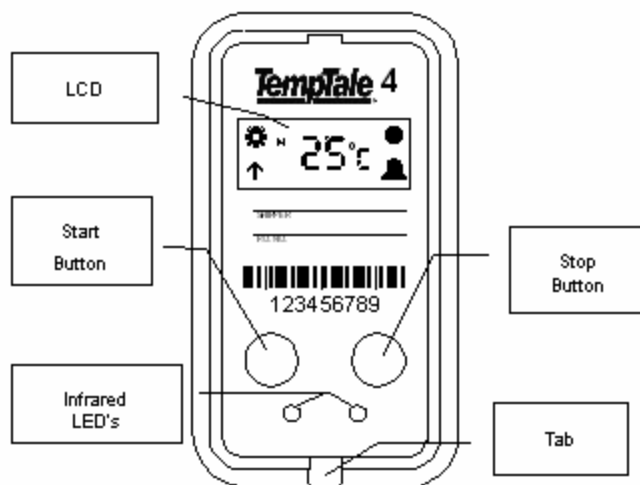


TempTale 4 Monitor

Instructions for Reading a TempTale 4 LCD

Press the **start** button. Five pieces of information will scroll, always in this order:

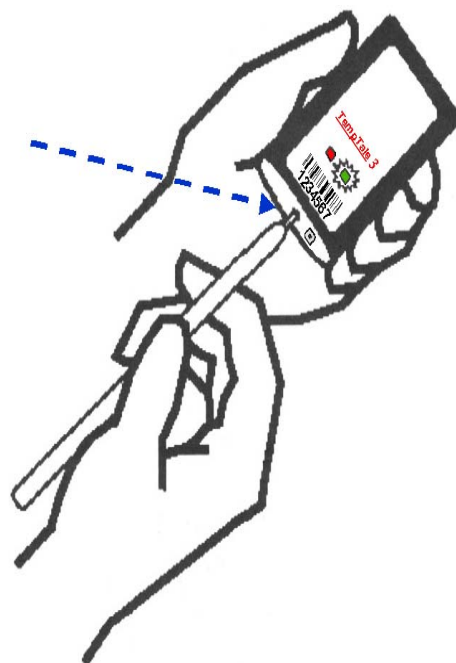
- Average temperature during the entire recording cycle
- Highest Temperature reached during the recording cycle
- Cumulative amount of time above the high temperature alarm
- Lowest Temperature reached during the recording cycle
- Cumulative amount of time below the low temperature alarm



TempTale 4 Monitor

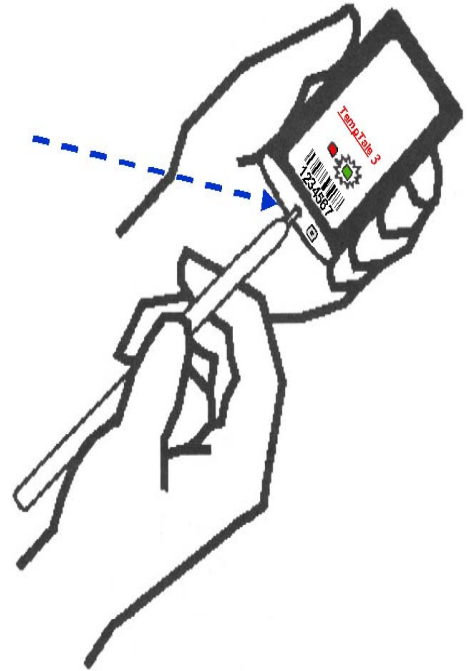
Starting a TempTale 3 Monitor

- Locate the start button on the end of the TempTale(start button is the black opening; do not insert anything into the opening with the silver ring.)
- While looking at the red & green lights on the face of the TempTale, depress the start button with a pen and release.
- When the monitor is activated the LEDs on the face of the monitor will flash **(8) eight** times.
- Wait about 2 minutes(start-up delay) and press the start button again, then it should blink **twice**. The monitor is now activated. Peel the paper from the adhesive strip & stick the TempTale to the product to reduce movement of the TempTale during shipment.



Instructions for Reading a TempTale 3 Monitor

- Locate the start button on the end of the TempTale(start button is the black opening; do not insert anything into the opening with the silver ring.)
- While looking at the red & green lights on the face of the TempTale, depress the start button with a pen and release.
- Either the red light or the green light will flash on the monitor.
- The green light indicates that the shipment was completed within the set temperature limits of the monitor. The red light indicates that temperature limits set on the monitor were exceeded.



TempTale Temperature Monitor (Green Light Check and Green Light Release Procedures)

1. **Green Light Check** - is performed to ensure that the product has arrived within its temperature range. This procedure is mandatory for all shipments to all locations in the Continental United States (CONUS) and Outside the Continent of the United States (OCONUS).

- o Inspect the package and contents for damage.
- o Open the container and remove the packing materials until you reach the TempTale monitor.
- o When looking at the face of the TempTale monitor, you will notice two holes towards the bottom of the label. One hole is a red light and the other hole is a green light.

Turn the bottom of the TempTale towards you. You will notice two holes. One hole will have a silver ring around it and the other hole will not.

- o While observing the lights on the face of the TempTale monitor. Insert a pen in the hole without the silver ring. One of the lights will flash at you.

o If the light is Green. Your product has arrived within its temperature range.

- o If the light is Red. Your product may have been compromised. Contact the _____ immediately, for further instructions.

Place the product into refrigeration and segregate from other good products until this particular product has been released for use.

- o The product is not release for use until you get approval from the _____.

- o Return the TempTale and any other material back to _____.

2. **Green Light Release** - is performed whenever the receiving activity is requesting to use the product immediately.

- o Inspect the package and contents for damage.
- o Prior to opening the container contact Distribution Operations Center at 301-619-4318.
- o Open the container and remove the packing materials until you reach the TempTale monitor.
- o When looking at the face of the TempTale monitor, you will notice two holes towards the bottom of the label. One hole is a red light and the other hole is a green light.
- o Turn the bottom of the TempTale towards you again you will notice two holes. One hole will have a silver ring around it and the other hole will not.
- o While observing the lights on the face of the TempTale monitor. Insert a pen in the hole without the silver ring. One of the lights will flash at you.
- o If the light is Green. Your product has arrived within its proper temperature range. At this time the _____ will release the product for use.
- o If the light is Red. Your product may have been compromised. The _____ will provide further instructions.